

NATURE AND SUMMARY OF THE ACTION

1. This is a stockholder derivative action brought by Plaintiff on behalf of Nominal Defendant Cassava Sciences, Inc. (“Cassava” or the “Company”) against members of its board of

directors (the “Board”) and members of upper management. The wrongdoing alleged herein has caused substantial damage to Cassava’s reputation, goodwill, and standing in the business community and has exposed Cassava to substantial potential liability for violations of federal securities laws and the costs associated with defending itself. The violations of the law outlined herein have also damaged Cassava in the form of, among other things, millions of dollars in losses to the Company’s market capitalization.

2. This action seeks to remedy wrongdoing committed by Cassava’s directors and officers from Cassava on September 12, 2020 through the present (the “Relevant Period”).

3. Cassava is a Delaware biotechnology corporation based in Austin, Texas, that develops drugs for neurodegenerative diseases. The Company’s lead therapeutic product candidate is a treatment for Alzheimer’s disease by the name of “simufilam,” which is designed to target a protein in the brain, filamin A (“FLNA”), and reverts it to a healthy conformation, combatting the effects of altered FLNA. Its lead investigational diagnostic product, called “SavaDx,” is a “novel way” to detect Alzheimer’s from a blood sample.

4. Currently, the Company has no source of revenue, and therefore its overall financial success depends heavily on the success of simufilam and SavaDx getting regulatory approval to get its lead therapeutic product candidates to market.

5. During the Relevant Period, the Individual Defendants caused the Company to submit manipulated data to the U.S. Food and Drug Administration (“FDA”) and made, or caused the Company to make, materially false and misleading statements to the investing public concerning the accuracy and reliability of data the Company was holding out as demonstrating simufilam’s efficacy.

6. However, during the Relevant Period, the Individual Defendants failed to disclose

or correct their statements that the data being presented to the public had been manipulated to show simufilam was more effective than it actually was.

7. The truth began emerging after the market closed on August 24, 2021, when a citizen petition submitted to the FDA became publicly available. The citizen petition stated that the data Cassava was presenting on simufilam's effectiveness contained "a series of anomalies that are suggestive of systemic data manipulation and misrepresentation[.]" and that the Company's practice of studying "Simufilam's effects in experiments conduct on postmortem human brain tissue . . . defies logic, and the data presented again have hallmarks of manipulation."

8. Before the market opened the next day, August 25, 2021, the Company issued a response to the allegations, defending itself in part by noting that "Cassava Sciences' plasma p-tau data from Alzheimer's patients was generated by Quanterix Corp. ["Quanterix"], an independent company, and presented at the recent Alzheimer's Association International Conference[.]"

9. Despite the Company's statement, the market received the allegations and response negatively, and the price per share of the Company's common stock dropped from \$117.83 at the close on August 24, 2021, to \$80.86 at the close on August 25, 2021. This decline of \$36.97 was approximately a 31.4% one-day drop in value.

10. On August 27, 2021, the truth fully emerged when Quanterix released a statement in response to Cassava, stating that "Quanterix'[s] sole responsibility with regard to this clinical study was to perform sample testing" and that "Quanterix or its employees did not interpret the test results or prepare the data charts presented by Cassava at the Alzheimer's Association International Conference (AAIC) in July 2021 or otherwise."

11. On this news, the Company's share price declined by \$12.51 per share from \$70.85 at the close on August 26, 2021 to \$58.34 at the close on August 27, 2021. This marked an

approximately 17.7% one-day drop in value.

12. The Individual Defendants breached their fiduciary duties by failing to correct and/or causing the Company to submit manipulated data to the FDA, and further, making or failing to correct these false and misleading statements of material fact. The Individual Defendants also willfully or recklessly caused the Company to fail to maintain an adequate system of internal controls.

13. During the Relevant Period, the Individual Defendants breached their fiduciary duties by personally making and/or causing the Company to make a series of materially false and misleading statements to the investing public regarding the Company's business, operations, and prospects. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements that failed to disclose, *inter alia*, that: (1) the quality and integrity of the data the Company used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; (5) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (6) due to the submission of manipulated data to the FDA, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (7) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements regarding simufilam were materially false and misleading at all relevant times.

14. As detailed herein, and as alleged in the ongoing federal securities class actions in

the Western District of Texas styled *Brazeau v. Cassava Sciences, Inc. et al.*, Case No. 1:21-cv-751; *Newell v. Cassava Sciences, Inc. et al.*, Case No. 1:21-cv-760; *Rao v. Cassava Sciences, Inc. et al.*, Case No. 1:21-cv-971; *Rein v. Cassava Sciences, Inc. et al.*, Case No. 1:21-cv-856; and *Zagami v. Cassava Sciences, Inc. et al.*, Case No. 1:21-cv-998, (the “Federal Securities Class Actions”), Cassava’s officers and directors substantially damaged the Company by filing false and misleading statements with manipulated and overstated data promoting the purported effectiveness of simufilam.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1331 because Plaintiff’s claims raise a federal question under Section 14(a) of the Exchange Act, 15 U.S.C. §78n(a)(1), Rule 14a-9 of the Exchange Act, 17 C.F.R. § 240.14a-9, and Section 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b), 78t(a) and 78t-1). This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367(a).

16. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that would not otherwise have such jurisdiction.

17. Venue is proper in this District because the Company is headquartered in this District and the Individual Defendants have been involved in business in this District. Further, Defendants’ actions have had an effect in this District.

THE PARTIES

Plaintiff

18. Plaintiff Patricia Matranga is, and has continuously been, a stockholder of Cassava during the wrongdoing complained of herein.

Nominal Defendant

19. Defendant Cassava Sciences, Inc. is a Delaware corporation with its principal executive offices at 7801 N. Capital of Texas Highway, Suite 260, Austin, TX 78731. Cassava's shares trade on the NASDAQ Capital Market ("NASDAQ") under the ticker symbol "SAVA."

Individual Defendants

20. Defendant Remi Barbier ("Barbier") has served as the Company's CEO, President, and Chairman of the Board since he started the Company in May 1998.¹ Based upon the Company's Schedule 14A filed with the SEC on March 31, 2021 (the "2021 Proxy"), as of March 16, 2021, Defendant Barbier beneficially owned 2,047,449 shares of common stock.² As the Company's common stock closed at \$52.16 per share on March 16, 2021, Defendant Barbier owned approximately \$107 million worth of Cassava stock as of that date. Defendant Barbier's stock ownership amounts to approximately 5% of total Cassava common stock outstanding.³ For the fiscal year ended December 31, 2020, Defendant Barbier received total compensation of \$936,120 from the Company, consisting of a \$920,000 salary and other compensation in the amount of \$16,120.⁴

21. The Company's 2021 Proxy described Defendant Barbier as follows:

Remi Barbier, the Company's founder, has served as President, Chief Executive Officer and Chairman of the Board of Directors since the Company's inception in May 1998. Prior to that time, Mr. Barbier helped in the growth or founding of Exelixis Inc. and ArQule, Inc., both publicly-traded drug development companies, and EnzyMed, Inc., a chemistry company sold to Albany Molecular Research, Inc.

¹ *Management*, Cassava Sciences, Inc., <https://www.cassavasciences.com/management>, (last visited Dec. 17, 2021).

² See Cassava 2021 Proxy at: <https://www.cassavasciences.com/static-files/914f6761-e590-4073-932a-d8f3c2ff7cbb>.

³ *Management*, Cassava Sciences, Inc., <https://www.cassavasciences.com/management>, (last visited Dec. 17, 2021).

⁴ *Id.*

Mr. Barbier is a trustee emeritus of the Carnegie Institute of Washington and the Santa Fe Institute and is on the Advisory Board of the University of California Institute for Quantitative Biosciences and BioVentures LLC, a life science incubator at the University of Arkansas for Medical Sciences. Mr. Barbier received his B.A. from Oberlin College and his M.B.A. from the University of Chicago.

Defendant Schoen

22. Defendant Eric J. Schoen (“Schoen”) has served as the Company’s CFO since October 2018.⁵ According to the 2021 Proxy, as of March 16, 2021, Defendant Schoen beneficially owned 58,550 shares of the Company’s common stock.⁶ For the fiscal year ended December 31, 2020, Defendant Schoen received total compensation of \$251,932 from the Company, consisting of a \$250,000 salary and other compensation in the amount of \$1,932.⁷ As the Company’s common stock closed at \$52.16 per share on March 16, 2021, Defendant Schoen owned approximately \$3.1 million worth of Cassava stock as of that date.

23. The Company’s 2021 Proxy described Defendant Schoen as follows:

Eric Schoen has served as Chief Financial Officer since October 2018. Prior to joining the Company, Mr. Schoen served in numerous financial leadership roles. Most recently, he served as Vice President, Senior Vice President, Finance and Chief Accounting Officer of Aspria Women’s Health Inc. (formerly Vermillion, Inc.), a publicly-held women’s health company, from 2011 to 2017. Mr. Schoen also began his career and spent nine years with PricewaterhouseCoopers in the audit and assurance, transaction services and global capital markets practices. Mr. Schoen received his B.S. in Finance from Santa Clara University.

Defendant Kupiec

24. Defendant James W. Kupiec (“Kupiec”) has served as the Company’s Chief Clinical Development Officer (“CCDO”) since January 2021.⁸

⁵ *Management*, Cassava Sciences, Inc., <https://www.cassavasciences.com/management>, (last visited Dec. 17, 2021).

⁶ *See* Cassava 2020 10-K: <https://www.cassavasciences.com/node/15256/html#Business>.

⁷ *See* Cassava 2021 Proxy at 15.

⁸ *See* Cassava 2021 Proxy at 15.

25. The Company's 2021 Proxy described Defendant Kupiec as follows:

James W. Kupiec, M.D. has served as Chief Clinical Development Officer since January 2021. Dr. Kupiec joined the Company after three decades of drug development experience at Pfizer, Sanofi and Ciba-Geigy. Dr. Kupiec previously served as Vice President, Global Clinical Leader for Parkinson's Disease and Clinical Head of the Neuroscience Research Unit for Pfizer, Inc., in Cambridge, MA. He joined Pfizer in 2000 after seven years with Sanofi, and two years with Ciba-Geigy Pharmaceuticals. During his 17-year career at Pfizer, Dr. Kupiec had extensive governance, business development, alliance and leadership responsibilities. Dr. Kupiec earned his BS with Honors in Biochemistry at Stony Brook University and his MD from the Albert Einstein College of Medicine. He completed his residency training at the Strong Memorial Hospital, University of Rochester School of Medicine, and is certified by the American Board of Internal Medicine. He served as an investigator on many clinical trials before transitioning to the pharmaceutical industry.

Defendant Friedmann

26. Defendant Nadav Friedmann ("Friedmann") joined Cassava as Chief Medical Officer in October 2001 and has served as a director since September 1998.⁹ As of March 16, 2021, Defendant Friedmann beneficially owned 572,076 shares of the Company's common stock, which represented approximately 1.4% of the Company's outstanding shares.¹⁰ As the Company's common stock closed at \$52.16 per share on March 16, 2021, Defendant Friedmann owned approximately \$29.8 million worth of Cassava stock as of that date. For the fiscal year ended December 31, 2020, Defendant Friedmann received total compensation of \$345,000 from the Company.¹¹

27. The Company's 2021 Proxy described Defendant Friedmann as follows:

Nadav Friedmann, Ph.D., M.D. has served as a director since September 1998. Dr. Friedmann has served as Chief Medical Officer since 2001. Dr. Friedmann was previously President and CEO of Daiichi Pharmaceutical Corporation. Dr. Friedmann has served as Vice President, Clinical Research at Xoma Corporation, and held various senior leadership

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

positions with Johnson & Johnson, including Head of its Biotechnology Research Center. Dr. Friedmann received his M.D. from the Albert Einstein College of Medicine and his Ph.D. in Biochemistry from the University of California, San Diego.

Defendant Gussin

28. Defendant Robert Z. Gussin (“Gussin”) has served as a director since March 2003.¹² He also serves as a member of the Audit Committee and the Compensation Committee.¹³ As of March 16, 2021, Defendant Gussin beneficially owned 119,225 shares of the Company’s common stock.¹⁴ As the Company’s common stock closed at \$52.16 per share on March 16, 2021, Defendant Gussin owned approximately \$6.2 million worth of Cassava stock as of that date. For the 2020 Fiscal Year, Defendant Gussin received \$75,924 in compensation from the Company, all in option awards.¹⁵

29. The Company’s 2021 Proxy described Defendant Gussin as follows:

Robert Z. Gussin, Ph.D. has served as a director since March 2003. Dr. Gussin worked at Johnson & Johnson for 26 years, most recently as Chief Scientific Officer and Corporate Vice President, Science and Technology from 1986 through his retirement in 2000. Dr. Gussin served on the board of directors of Duquesne University and the advisory boards of the Duquesne University Pharmacy School and the University of Michigan Medical School Department of Pharmacology. Dr. Gussin received his B.S. and M.S. degrees and D.Sc. with honors from Duquesne University and his Ph.D. in Pharmacology from the University of Michigan, Ann Arbor.

Defendant O’Donnell

30. Defendant Michael J. O’Donnell (“O’Donnell”) has served as a director since June 1998.¹⁶ As of March 16, 2021, Defendant O’Donnell beneficially owned 83,223 shares of the

¹² *Board of Directors*, Cassava Sciences, Inc., <https://www.cassavasciences.com/corporate-governance/board-of-directors>, (last visited Dec. 17, 2021).

¹³ *Id.*

¹⁴ *See* Cassava 2021 Proxy at 18.

¹⁵ *See* Cassava 2021 Proxy at 26.

¹⁶ *Board of Directors*, Cassava Sciences, Inc., <https://www.cassavasciences.com/corporate-governance/board-of-directors>, (last visited Dec. 17, 2021).

Company's common stock.¹⁷ As the Company's common stock closed at \$52.16 per share on March 16, 2021, Defendant O'Donnell owned approximately \$4.3 million worth of Cassava common stock as of that date.

31. The Company's 2021 Proxy described Defendant O'Donnell as follows:

Michael J. O'Donnell, Esq. has served as a director since June 1998. Mr. O'Donnell has been a member of the law firm of Morrison & Foerster LLP since 2011. Morrison & Foerster LLP is the Company's corporate counsel and provides legal services to the Company. Mr. O'Donnell serves as corporate counsel to numerous public and private biopharmaceutical and life sciences companies. Previously, Mr. O'Donnell was a member of Wilson Sonsini Goodrich & Rosati. Mr. O'Donnell received his J.D., cum laude, from Harvard University and his B.A. from Bucknell University, summa cum laude.

Defendant Robertson

32. Defendant Sanford R. Robertson ("Robertson") has served as a director since 1998.¹⁸ He also serves as a member of the Audit Committee, the Compensation Committee and the Nominating and Governance Committee.¹⁹ As of March 16, 2021, Defendant Sanford beneficially owned 1,027,943 shares of the Company's common stock.²⁰ Defendant Sanford's stock ownership amounts to approximately 2.6% of the Company's outstanding common stock.²¹ As the Company's common stock closed at \$52.16 per share on March 16, 2021, Defendant Robertson owned approximately \$53.6 million worth of Cassava common stock as of that date. For the 2020 Fiscal Year, Defendant Robertson received \$75,924 in compensation from the

governance/board-of-directors, (last visited Dec. 17, 2021).

¹⁷ See Cassava 2021 Proxy at 18.

¹⁸ *Board of Directors*, Cassava Sciences, Inc., <https://www.cassavasciences.com/corporate-governance/board-of-directors>, (last visited Dec. 17, 2021).

¹⁹ *Id.*

²⁰ See Cassava 2021 Proxy at 18.

²¹ *Id.*

Company, all in options awards.²²

33. The Company's 2021 Proxy described Defendant Robertson as follows:

Sanford R. Robertson has served as a director since September 1998. Mr. Robertson has been a partner of Francisco Partners, a technology buyout fund, since 1999. Prior to founding Francisco Partners, Mr. Robertson was the founder and chairman of Robertson, Stephens & Company, a technology investment bank sold to BankBoston in 1998. Mr. Robertson is the lead director of Salesforce.com, a publicly-held provider of enterprise cloud computing applications. Mr. Robertson received his B.A. and M.B.A. degrees with distinction from the University of Michigan.

Defendant Scannon

34. Defendant Patrick J. Scannon ("Scannon") has served as a director since 2007.²³

During the Relevant Period, Defendant Scannon was a member of the Audit Committee.²⁴ As of March 16, 2021, Defendant Scannon beneficially owned 89,144 shares of the Company's common stock.²⁵ As the Company's common stock closed at \$52.16 per share on March 16, 2021, Defendant Scannon owned approximately \$4.6 million worth of Cassava common stock as of that date. For the 2020 Fiscal Year, Defendant Scannon received \$37,962 in compensation from the Company, all in option awards.²⁶

35. The Company's 2021 Proxy described Defendant Scannon as follows:

Patrick J. Scannon, M.D., Ph.D. has served as a director since December 2007. Dr. Scannon is one of the founders of XOMA. From 2006 to 2016, Dr. Scannon was Executive Vice President, Chief Biotechnology Officer of XOMA. From 1993 to 2006, Dr. Scannon served as Chief Scientific and Medical Officer of XOMA. Dr. Scannon retired from XOMA and resigned from XOMA's board of directors in 2016. Dr. Scannon received his Ph.D. in organic chemistry from the University of

²² See Cassava 2021 Proxy at 26.

²³ *Board of Directors*, Cassava Sciences, Inc., <https://www.cassavasciences.com/corporate-governance/board-of-directors>, (last visited Dec. 17, 2021).

²⁴ See Cassava 2021 Proxy at 18.

²⁵ *Id.*

²⁶ See Cassava 2021 Proxy at 26.

California, Berkeley and his M.D. from the Medical College of Georgia.

36. Collectively, Defendants Gussin, Robertson, and Scannon are referred to herein as the “Audit Committee Defendants.”

37. Collectively, Defendants Barbier, Friedmann, Gussin, O’Donnell, Robertson, and Scannon are referred to herein as the “Director Defendants.”

38. Collectively, Defendants Barbier, Friedmann Kupiec, Schoen, Gussin, O’Donnell, Robertson, and Scannon are referred to herein as the “Individual Defendants.”

39. The Individual Defendants, because of their positions with Cassava, possessed the power and authority to control the contents of Cassava’s reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Individual Defendants was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance, and each had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and/or misleading.

SUBSTANTIVE ALLEGATIONS

Background

40. Cassava is a biotechnology company that has a product portfolio including simufilam, its lead therapeutic product candidate, and SavaDx, its lead investigational diagnostic product candidate. Simufilam is an Alzheimer’s treatment, and SavaDx is a test to detect the presence of Alzheimer’s before the appearance of clinical symptoms.

41. One of the Company's much larger competitors, Biogen Inc. ("Biogen"), recently received FDA approval for its Alzheimer's treatment, Aduhelm. However, simufilam represents an appealing potential alternative to Aduhelm, if it were to receive FDA approval, given that it is taken orally, rather than intravenously, and that it is expected to be much cheaper, with Aduhelm costing approximately \$56,000 per patient per year.

42. Cassava is under great pressure to get one or both of its lead product candidates to market, given that, according to the Company's most recent Form 10-Q filed with the SEC on August 4, 2021, Cassava "ha[s] yet to generate any revenues from product sales" and "ha[s] an accumulated deficit of \$183.6 million at June 30, 2021."

43. Immediately prior to the Relevant Period, the Company was finalizing the results of its simufilam Phase 2b clinical trials as it attempted to advance to Phase 3 of the FDA approval process. While the clinical trials the Company conducted purportedly showed simufilam's effectiveness, later analysis presented in a citizen's petition to the FDA would show that the data from these trials had been manipulated. According to the citizen petition, no other labs were able to confirm Cassava's research regarding simufilam.

The Individual Defendants' False and Misleading Statements

September 14, 2020 Press Release

44. On September 14, 2020, the Company issued a press release announcing the final results of its Phase 2b clinical study of simufilam. The press release stated, in relevant part:

Cassava Sciences, Inc. (Nasdaq: SAVA) today announced final results of a Phase 2b study with its lead drug candidate, simufilam, in Alzheimer's disease. In a clinical study funded by the National Institutes of Health (NIH), **simufilam significantly improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease. The ability to improve multiple biomarkers from distinct biological pathways with one drug has never been shown before in patients with Alzheimer's disease.** Study results are expected to be published in a peer-reviewed publication. Simufilam is the first of a new class of drug

compounds that bind to a protein called Filamin A.

“Filamin-binding molecules are new to Alzheimer’s research and may represent an important advance if these data can be replicated in larger studies,” said Jeffrey Cummings, M.D., Sc.D., Founding Director of the Cleveland Clinic Lou Ruvo Center for Brain Health, and Chambers Professor of Brain Science at the University of Nevada, Las Vegas. “I am pleased to see early evidence of disease-modifying effects in patients with this investigational drug. The data appear to represent a step forward toward urgently needed treatments for Alzheimer’s disease.”

In addition, Alzheimer’s patients treated with simufilam showed directional improvements in tests of remembering new information, versus patients on placebo. **Improvements in cognition correlated most strongly with decreases in P-tau181, a biomarker that, when elevated, leads to tangles in the brain. Simufilam decreased brain levels of Ptau-181 by 8-11%, versus placebo.**

In this study, **Alzheimer’s patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant ($p < 0.05$) improvements in biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer’s patients who took placebo.** In addition, Alzheimer’s patients treated with simufilam showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%). **Cognitive improvements correlated most strongly ($R^2 = 0.5$) with decreases in P-tau181. The study achieved a 98% response rate, defined as the proportion of study participants taking simufilam who showed improvements in biomarkers.**

“The clinical data suggest simufilam may be slowing disease progression in Alzheimer’s patients,” said Nadav Friedmann, PhD/MD, Chief Medical Officer, Cassava Sciences. “This exciting possibility will need to be evaluated in future collaborations with patients, physicians, advisors and others.”

“Other than a few drugs to help ease the decline, there’s really nothing out there to treat people with Alzheimer’s,” said **Remi Barbier, Chairman, President & CEO, Cassava Sciences.** “**The improvement on multiple biomarkers in this clinical study is a first** and offers hope that simufilam has potential to become a transformative treatment for people with Alzheimer’s disease.”

(Emphasis added.)

February 2021 Press Releases

45. On February 2, 2021, the Company announced the results of an interim analysis

from an open-label study of simufilam.²⁷ The press release contained statements attributed to Defendants Barbier and Friedmann and stated, in relevant part:

Cassava Sciences, Inc. (Nasdaq: SAVA) today announced results of an interim analysis from an open-label study of simufilam, its lead drug candidate for the treatment of Alzheimer's disease. Patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues.

In a clinical study funded by the National Institutes of Health and conducted by Cassava Sciences, six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6. In these same patients, simufilam also improved dementia-related behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6.

Alzheimer's is a progressive disease. Over time, a patient's cognition will always worsen. "Experience based on longitudinal studies of ambulatory patients with mild to moderate Alzheimer's disease suggest that scores on ADAS-cog decline by 6 - 12 points per year", according to FDA's Prescription Information sheet for ARICEPT® (donepezil), a drug approved for the treatment of dementia of the Alzheimer's type1.

"We could not be more pleased with these interim results," said Remi Barbier, President & CEO. "We would have been satisfied to show simufilam stabilizes cognition in patients over 6 months. An improvement in cognition and behavior tells us this drug candidate has potential to provide lasting treatment effects for people living with Alzheimer's disease. It's an exciting development."

The safety profile of simufilam in the interim analysis was consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

"Today's data once again suggests simufilam could be a transformative, novel therapeutic," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide a treatment benefit following 6 months of dosing."

(Emphasis added.)

²⁷ Cassava Sciences' *Simufilam Improves Cognition and Behavior in Alzheimer's Disease in Interim Analysis of Open-label Study*, CASSAVA SCIENCES, Inc. (Feb. 2, 2021), <https://www.cassavasciences.com/node/15101/pdf> (last visited Dec. 20, 2021).

46. Following the Company's February 2, 2021 announcement, the price per share of the Company's common stock skyrocketed, from \$22.99 at the close of trading on February 1, 2021 to close on February 2, 2021 at \$55.44. At the close of the markets on February 3, 2021 the price per share of the Company's common stock was \$87.95, an increase of approximately 383% from its February 1, 2021 price.

47. Then on February 8, 2021, the Company issued another press release announcing, "Significant Program Progress and Expected Key Milestones in 2021 for its Clinical Program in Alzheimer's Disease."²⁸ The press release stated, in relevant part:

"We started 2021 with tremendous momentum, led by results of a 6-month interim analysis from an open-label study of simufilam, our drug candidate for Alzheimer's disease," said Remi Barbier, President & CEO. "I believe the rest of the year may be equally exciting."

Cassava Sciences' strategic focus for 2021 is to advance simufilam in a Phase 3 clinical program in Alzheimer's disease, to expand drug manufacturing capabilities in support of the clinical program, and to continue to lead the Company to deliver the full potential of its product portfolio.

Cassava Sciences' 2021 Scientific and Clinical Outlook

* * *

Expected progress and key milestones in 2021 across Cassava Sciences' product portfolio are summarized below.

- ***Based on recent positive clinical results*** and inbound demand from clinical sites, patients, and their caregivers, Cassava Sciences plans to expand the size of the ongoing open-label study of simufilam. The target enrollment will be increased by up to 50 additional patients with mild-to-moderate Alzheimer's disease, for a total target enrollment of up to 150 patients.
- Cassava Sciences has enrolled approximately 80 patients in the open-label study to date. To accommodate increased enrollment, the Company plans to open new clinical sites across the U.S. and Canada.

²⁸ "Cassava Sciences Announces Significant Program Progress and Expected Key Milestones in 2021 for Its Clinical Program in Alzheimer's Disease", CASSAVA SCIENCES, Inc. (Feb. 8, 2021), <https://www.cassavasciences.com/node/15121/pdf>.

* * *

- *Cassava Sciences' clinical and regulatory strategy for simufilam is progressing as planned. In January 2021, the Company concluded a successful End-of-phase 2 (EOP2) meeting with the U.S Food and Drug Administration (FDA). The purpose of the EOP2 was to gain general agreement around a Phase 3 program to treat Alzheimer's disease dementia.*

* * *

- Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021.

* * *

- Cassava Sciences expects to initiate a validation study with SavaDx, its investigational diagnostic for the detection of Alzheimer's disease.

* * *

Other Expected Milestones and Announcements for 2021

- *Cassava Sciences expects to announce publication of Phase 2b results in a peer-reviewed technical journal.*
- Net cash use for full-year 2021 is expected to be in the range of \$20 to \$25 million, depending on enrollment rates in its clinical programs and other factors. On December 31, 2020, unaudited cash and cash equivalents were approximately \$93 million.

(Italicized emphasis added.)

48. On February 10, 2021, Cassava announced an offering of 4,081,633 shares of its common stock priced at \$49 per share for a total of approximately \$200 million.²⁹ On February 12, 2021, the Company completed the offering with net proceeds of \$189.7 million.³⁰

²⁹ "Cassava Sciences Announces \$200 Million Registered Direct Offering of Common Stock", CASSAVA SCIENCES, INC. (Feb. 10, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-200-million-registered-direct> (last visited Dec. 20, 2021).

³⁰ "Cassava Sciences Announces Closing of \$200 Million Registered Direct Offering", CASSAVA SCIENCES, INC. (Feb 12, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-closing-200-million-registered-direct> (last visited Dec. 20, 2021).

49. On February 22, 2021, Cassava issued a press release announcing a “Positive End-of-Phase 2 Meeting with FDA and Outlin[ing a] Pivotal Phase 3 Program for Simufilam in Alzheimer’s Disease.”³¹ The press release stated, in relevant part:

- Two Upcoming Phase 3 Studies and a Previously Completed Phase 2 Program Support a New Drug Application Filing for Simufilam in Alzheimer’s disease –

- Agreement Reached to Use ADAS-Cog as Co-Primary Efficacy Endpoint –

- Pivotal Phase 3 Program Remains On-track to be Initiated 2nd Half 2021 –

... Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company developing product candidates for Alzheimer’s disease, *today announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for simufilam*, its lead drug candidate for the treatment of Alzheimer’s disease. *Official EOP2 meeting minutes indicate FDA and Cassava Sciences agree on key elements of a pivotal Phase 3 clinical program in support of a New Drug Application (NDA) filing for simufilam* in Alzheimer’s disease. Agreements reached during the EOP2 meeting show a clear path forward for advancing simufilam into Phase 3 studies in the second half of 2021.

“For over 10 years we’ve been doing basic research and early drug development with simufilam,” said Remi Barbier, President & CEO. “We are excited to finally advance simufilam into pivotal Phase 3 clinical studies in people with Alzheimer’s disease. We believe the underlying science is solid, the drug appears safe and the clinical roadmap makes sense. We’ve crossed the Rubicon.”

“We appreciate the valuable guidance and flexibility FDA has provided,” added Jim Kupiec, MD, Cassava Sciences’ Chief Clinical Development Officer. “We look forward to continuing a collaborative dialogue throughout the pivotal Phase 3 clinical development program.”

Simufilam is a novel drug, discovered at Cassava Sciences, that targets both neuroinflammation and neurodegeneration. *The EOP2 meeting discussion was supported by years of scientific and clinical data, including positive results from a previously completed Phase 2 clinical program with simufilam in Alzheimer’s disease. In a double-blind, randomized, placebo-controlled Phase 2b study, simufilam demonstrated robust effects on primary and secondary outcome measures, with no safety issues. Recently, the Company announced that*

³¹ “Cassava Sciences Announces Positive End-of-Phase 2 Meeting with FDA and Outlines Pivotal Phase 3 Program for Simufilam in Alzheimer’s Disease”, CASSAVA SCIENCES, INC. (Feb. 22, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-positive-end-phase-2-meeting-fda-and->

simufilam improved cognition in subjects with Alzheimer’s disease in a 6-month interim analysis of an open-label study, with no safety issues.

The EOP2 meeting took place mid-January. FDA attendees included Robert Temple, MD, Deputy Center Director for Clinical Science and Senior Advisor in the Office of New Drugs; Billy Dunn, MD, Director, Office of Neuroscience; Eric Bastings, MD, Director, Division of Neurology, and others.

Official meeting minutes confirm that Cassava Sciences and FDA are aligned on key elements of a Phase 3 clinical program for simufilam. ***FDA has agreed that the completed Phase 2 program, together with an upcoming and well-defined Phase 3 clinical program, are sufficient to show evidence of clinical efficacy for simufilam in Alzheimer’s disease.*** There is also agreement that the use of separate clinical scales to assess cognition (ADAS-cog1) and function (ADCS-ADL2) are appropriate co-primary endpoints of efficacy. A clinical scale that combines cognition and function, such as iADRS3, is a secondary efficacy endpoint.

(Italicized emphasis added.)

March 2021 Press Releases

50. On March 9, 2021, Cassava “announced it has entered into a drug supply agreement with Evonik Industries AG for simufilam. Under the agreement, Evonik will supply Cassava Sciences with large-scale, clinical-grade quantities of simufilam, a drug candidate for the treatment of Alzheimer’s disease.”³²

51. Then, on March 23, 2021, the Company issued a press release touting its “financial results for the year ended December 31, 2020 and provided business updates.”³³ The press release stated, in relevant part:

“In Q1 2021 we announced that our lead drug candidate, simufilam, improved cognition scores in 50 patients with Alzheimer’s disease who completed at least 6 months of open-label treatment,” ***said Remi Barbier***, President & CEO. “In mid-2021, we look forward to announcing cognition scores in patients who’ll have

³² “Cassava Sciences Announces Pharmaceutical Supply Agreement for Simufilam”, CASSAVA SCIENCES, INC. (Mar. 09, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-pharmaceutical-supply-agreement>.

³³ “Cassava Sciences Announces Full-Year 2020 Financial Results and Business Highlights”, CASSAVA SCIENCES, INC. (Mar. 23, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-full-year-2020-financial-results-and>.

completed at least 12 months of open-label treatment with simufilam. To our knowledge, no drug has stabilized, much less improved, cognition scores over 12 months in patients with Alzheimer’s disease. For this reason, I feel there is a sense of anticipation around the upcoming release of 12-month clinical data from our open-label study, as well as our plans to conduct a pivotal Phase 3 program with simufilam in the second half of 2021. ***With solid science, the right people in place, cash in the bank and a clinical roadmap that makes sense, I think Cassava Sciences is positioned to becoming a premier organization to serve patients with Alzheimer’s disease.***”

“We have approximately \$280 million in cash on our balance sheet, against expected cash use of approximately \$20 to \$25 million in 2021,” said Eric Schoen, Chief Financial Officer. “We believe our cash levels support a pivotal Phase 3 clinical program of simufilam in Alzheimer’s disease.”

(Italicized emphasis added).

March 23, 2021 Form 10-K

52. Also on March 23, 2021, Cassava filed its annual report for the 2020 Fiscal Year on Form 10-K with the SEC (the “2020 10-K”).³⁴ The 2020 10-K was signed by Defendants Barbier, Schoen, Friedmann, Gussin, O’Donnell, Robertson, and Scannon³⁵ and contained certifications, signed by Defendants Barbier and Schoen, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Exchange Act and the Sarbanes-Oxley Act of 2002 (“SOX”) attesting to the accuracy of the financial statements contained in the 2020 10-K, the disclosure of any material changes to the Company’s internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors³⁶.

53. The Company’s 2020 10-K contained the following general warning regarding the risks involved with developing its product candidates:

Since 2017, we have concentrated a substantial portion of our research and

³⁴ Cassava Sciences, Inc. 2020 Form 10-K, CASSAVA SCIENCES, INC. (Dec. 31, 2020), <https://www.cassavasciences.com/node/15256/html>.

³⁵ *Id.* at 97.

³⁶ *Id.* at Exhibits 31.1, 31.1, and 32.1.

development efforts on the treatment and detection of Alzheimer's disease, an area of research that has seen significant failure rates. Further, our product candidates are based on new scientific approaches and novel technology, which makes it difficult to predict the time and cost of product candidate development and likelihood of success.

Since 2017, we have concentrated a substantial portion of our research and development efforts on experimental methods for the treatment and detection of Alzheimer's disease. Prior efforts by biopharmaceutical companies to develop new treatments for Alzheimer's disease have seen very limited clinical success. No new treatments have been approved for Alzheimer's disease since 2003, and since that time, while many large clinical studies have been completed, no drug candidate has shown clear evidence of clinical efficacy in large, Phase 3 clinical studies. FDA-approved drugs for Alzheimer's disease only address symptoms, and there are no FDA-approved disease modifying therapeutics available for patients with Alzheimer's disease. Notwithstanding these substantial challenges to date, we seek to improve brain health by addressing the neurodegeneration and neuroinflammation components of Alzheimer's disease. Our lead drug candidate for Alzheimer's disease is based on a new approach of stabilizing – but not removing – a critical protein in the brain. We cannot be certain that our novel technologies will lead to an approvable or marketable product. In addition, because FDA has limited comparators to evaluate our lead drug candidate, we could experience a longer than expected regulatory review process and increased development costs.

(Italicized emphasis added).

54. Furthermore, the 2020 10-K contained the following generic warning regarding the risk that its product candidates could fail to demonstrate either efficacy or safety:

Our clinical studies may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization.

* * *

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical studies, and results of early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. The results of clinical studies in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors,

including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, and other clinical study protocols and the rate of dropout among clinical study participants. Open-label extension studies may also extend the timing and cost of a clinical study substantially. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical studies. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier studies. This is particularly true in neurodegenerative diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical studies are never approved by regulatory authorities for commercialization.

* * *

In addition, even if such clinical studies are successfully completed, we cannot guarantee that FDA or foreign regulatory authorities will interpret the results as we do, and more studies could be required before we submit our product candidates for approval. To the extent that the results of the studies are not satisfactory to FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional studies in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit its commercial potential.

(Italicized emphasis added).

55. Finally, the Company's 2020 10-K contained the following statement regarding the Company's internal controls:

Evaluation of disclosure controls and procedures.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. ***Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission, or SEC, rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.***

Management's annual report on internal control over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2020. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework (2013 Framework).

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on the COSO criteria, we believe our internal control over financial reporting as of December 31, 2020 was effective.

* * *

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(Bolded italicized emphasis added.)

April 21, 2021 Press Release

56. On April 21, 2021, the Company issued a press release announcing its financial results for the fiscal quarter ended March 31, 2021.³⁷ The press release stated, in relevant part:

- 9 Month Interim Analysis of Open-label Study to be Presented at a Major Scientific Conference in July 2021 as an Oral Presentation –

- Initiation of Pivotal Phase 3 Program Remains On-track for 2nd Half 2021 –

- Initiation of Cognition Maintenance Study On-track for June 2021 –

- Cash and cash equivalents were \$282.2 million at March 31, 2021 –

. . . Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the first quarter ended March 31, 2021 and guidance regarding the release of new clinical data with simufilam. Simufilam is the Company's lead drug candidate to treat Alzheimer's disease.

"Alzheimer's is a progressive disease, so a patient's cognition is expected to worsen over time," said Remi Barbier, President & CEO. "Patients' cognition scores actually improved following 6 months of open-label treatment with simufilam. Showing similar drug effects following 9 months of open-label treatment would be remarkable, yet consistent with simufilam's mechanism of action. Eventually, we'd like this drug candidate to benefit cognition for a year or longer."

In July 2021, Cassava Sciences plans to announce results of a pre-specified interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 9 months of open-label drug treatment. The Company will present these data July 26 - 29th at the 2021 Alzheimer's Association International Conference (AAIC). AAIC's scientific committee has invited the Company's scientists to present the dataset as an oral presentation.

About the Open-label Study with Simufilam

In March 2020, Cassava Sciences initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The open-label study is intended to monitor the long-term safety and tolerability of simufilam 100 mg

³⁷ "Cassava Sciences Reports First Quarter 2021 Financial Results and Announces Guidance on Clinical Data Release", CASSAVA SCIENCES, INC. (Apr. 21, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-reports-first-quarter-2021-financial-results>.

twice-daily for 12 months or longer in patients with Alzheimer's disease. Another study objective is to measure changes in cognition on ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study's clinical protocol has pre-specified cognition measurements at 6, 9 and 12 months.

The study's target enrollment is approximately 150 subjects with mild-to-moderate Alzheimer's disease (recently increased by 50 subjects). One-hundred subjects have enrolled in this study across multiple clinical sites in the U.S. and Canada.

On February 2, 2021, Cassava Sciences announced positive results of a first interim analysis that summarizes clinical data on the first 50 subjects to complete 6 months of open-label treatment. Patients' cognition scores improved from baseline following 6 months of simufilam treatment, with no safety issues. Six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6.

In September 2021, Cassava Sciences plans to announce results of an interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 12 months of open-label drug treatment.

About the Cognition Maintenance Study (CMS)

In June 2021, Cassava Sciences plans to initiate a double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease. Patients who have completed at least one year of open-label treatment with simufilam qualify to enroll in the Cognition Maintenance Study (CMS). Study subjects in the CMS will be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment.

(Italicized emphasis added.)

June 21, 2021 Press Release

57. On June 21, 2021, the Company issued a press release providing a "Mid-Year Corporate Update[.]"³⁸ The press release stated, in relevant part:

- **Open-label Study Completes Patient Enrollment**
- **Cognition Maintenance Study Initiated May 2020, now 30% Enrolled**
- **6-month Biomarker Data to be Presented at AAIC Conference in July**

³⁸ "Cassava Sciences Provides Mid-Year Corporate Update, Clinical Development Progress and Announces Guidance on Clinical Data Release", CASSAVA SCIENCES, INC. (Jun. 21, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-provides-mid-year-corporate-update-clinical>.

- **9-month Safety & Cognition Data to be Presented at AAIC Conference**
- **Clinical Results with SavaDx to be Presented at AAIC Conference**
- **Phase 3 Program Initiation Remains On-track for 2nd Half 2021**

...Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today announced a mid-year update that highlights clinical development progress and provides guidance on upcoming data releases for simufilam and SavaDx. Simufilam is Cassava Sciences' lead drug candidate to treat Alzheimer's disease; SavaDx is an investigational diagnostic candidate to detect Alzheimer's with a simple blood test.

“Patients with Alzheimer’s want clear and present evidence of drug efficacy,” said Remi Barbier, President & CEO. “The recent regulatory approval of a new drug for Alzheimer’s was a bit of a donnybrook over this very topic. Our clinical strategy with simufilam is to show real-world safety and efficacy by conducting both, randomized controlled trials, and an on-going open-label study. Ideally, biomarker and cognition data from our studies converge and result in health benefits for patients.”

Clinical progress across Cassava Sciences' product portfolio is summarized below.

Update on Open-label Study with Simufilam

* * *

The open-label study has completed its target enrollment of 150 subjects. By physician and patient request, clinical sites may continue to enroll additional subjects up through the initiation of the Company's Phase 3 pivotal program of simufilam.

Guidance on Clinical Data Release

Cassava Sciences plans to announce results of an interim analysis on safety and cognition for the first 50 subjects to complete 9 months of open-label drug treatment. These cognition data will be presented at the 2021 Alzheimer's Association International Conference (AAIC) in Denver, CO, the week of July 26-30th. The scientific committee of AAIC has invited the Company's scientists to present these data as an oral presentation.

Cassava Sciences will also present at AAIC biomarker data from the open-label study, including:

- Biomarkers of Alzheimer's disease: amyloid beta42, total tau, P-tau181.
- Biomarkers of neurodegeneration: neurogranin, neurofilament light chain (NfL).
- Biomarkers of neuroinflammation: YKL-40, sTREM2 and HMGB1.

Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from twenty-five study subjects who underwent a small volume lumbar puncture at baseline and again after completing 6 months of open-label drug treatment.

* * *

Update on the Phase 3 Clinical Program

* * *

Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021. A clinical research organization (CRO) has been selected and will be publicly announced shortly. Large-scale, cGMP drug production capabilities are in-place to support the Phase 3 clinical program.

(Italicized emphasis added; some original emphasis removed.)

July 2021 Press Releases

58. On July 26, 2021, the Company issued a press release titled “Cassava Sciences Announces Positive Data with SavaDx from a Randomized Controlled Phase 2b Study of Simufilam[.]”³⁹ The press release stated, in relevant part:

- **SavaDx Detected Significant Changes in Plasma Levels of Altered Filamin A in Patients with Alzheimer's Disease Before and After Simufilam Treatment**
- **Simufilam 100 mg and 50 mg Reduced Plasma Levels of Altered Filamin A in Alzheimer's Patients 48% (p=0.003) and 44% (p=0.02) Respectively**
- **Plasma Results with SavaDx Track Plasma Results with p-Tau181**
- **Plasma Data Provide Evidence of Target Engagement**
- **Poster Presentation at AAIC Today**

... Cassava Sciences, Inc. (Nasdaq: SAVA) today announced positive clinical data with SavaDx, an investigational diagnostic/biomarker to detect Alzheimer's disease with a simple blood test. SavaDx was used to measure plasma levels of altered filamin A before and after simufilam treatment in patients with Alzheimer's

³⁹ “Cassava Sciences Announces Positive Data with SavaDx from a Randomized Controlled Phase 2b Study of Simufilam”, CASSAVA SCIENCES, INC. (Jul. 26, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-positive-data-savadx-randomized>.

disease. In this Phase 2b randomized, controlled trial sponsored by the National Institutes of Health (NIH), simufilam significantly reduced plasma levels of altered filamin A in Alzheimer's patients treated for 28 days. Plasma levels of p-tau181 also dropped significantly in these same patients.

Simufilam 100 mg and 50 mg reduced plasma levels of altered filamin A by 48% ($p=0.003$) and 44% ($p=0.02$) respectively, versus placebo. Additionally, simufilam 100 mg and 50 mg reduced plasma levels of p-tau181 by 17% ($p=0.01$) and 15% ($p=0.02$) respectively, versus placebo. Plasma p-tau181 is a biomarker that is known to be elevated in Alzheimer's disease.

"We believe altered filamin A is a major culprit in Alzheimer's disease," said Remi Barbier, President & CEO. "Before simufilam treatment, SavaDx detected high plasma levels of altered filamin A in patients. After simufilam treatment, levels dropped significantly. We believe these data provide clear evidence that simufilam binds to and engages its intended target to produce treatment effects."

Treatment effects on CSF biomarkers for this Phase 2b study have been previously reported.

(Italicized emphasis added.)

59. On July 29, 2021, Cassava issued a press release, one of two released that day, titled, "Cassava Sciences Announces Positive Biomarker Data with Simufilam in Alzheimer's Disease[.]"⁴⁰ The press release stated, in relevant part:

- **Simufilam Significantly Improved Biomarkers in Alzheimer's Patients Treated for 6 Months**
- **Robust Improvements Seen in All Measured Biomarkers of Disease, Neurodegeneration and Neuroinflammation ($p < 0.00001$)**
- **Biomarker Improvements Track with Cognitive Improvements**
- **Oral Presentation at AAIC Today**

... Cassava Sciences, Inc. (Nasdaq: SAVA) *today announced positive biomarker data from an open-label study of simufilam*, the Company's investigational drug for the treatment of Alzheimer's disease.

⁴⁰ "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease", CASSAVA SCIENCES, INC. (Jul. 29, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-positive-cognition-data-simufilam>.

In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved all measured biomarkers in patients with Alzheimer's disease following 6 months of open-label treatment. Biomarkers are objective biological data. There are no placebo effects.

Cerebrospinal fluid (CSF) biomarkers of disease pathology, t-tau and p-tau181, decreased 38% and 18%, respectively (both $p < 0.00001$). CSF biomarkers of neurodegeneration, neurogranin and Nfl, decreased 72% and 55%, respectively (both $p < 0.00001$). CSF biomarkers of neuroinflammation, sTREM2 and YKL-40, decreased 65% and 44% (both $p < 0.00001$). CSF biomarker data were collected from 25 patients with mild-to-moderate Alzheimer's disease who completed 6 months of simufilam treatment in an on-going open-label study.

"Six months of simufilam treatment robustly improved brain biomarkers," said Remi Barbier, President & CEO. "In this same study simufilam also improved cognition. These data suggest simufilam has potential to provide durable treatment effects for people living with Alzheimer's."

(Italicized emphasis added.).

Second July 29, 2021 Press Release

60. On July 29, 2021, Cassava issued another press release titled, "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease[.]"⁴¹ The Company touted the purportedly positive data in the press release, stating in relevant part:

- **Simufilam Significantly Improves Cognition in Patients with Alzheimer's in Interim Analysis of Open-label Study at 9 Months**
- **Cognition Improved 3.0 Points on ADAS-Cog at 9 Months ($p < 0.001$)**
- **Cognitive Improvements Track with Biomarker Improvements**
- **No Behavior Disorders in Over 50% of Patients**
- **No Safety Issues**
- **Improvements in Cognition, Biomarkers and Behavior Suggest Highly Encouraging Treatment Effects**
- **Oral Presentation at AAIC Today**

⁴¹ "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease", CASSAVA SCIENCES, INC. (Jul. 29, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-positive-cognition-data-simufilam>.

... Cassava Sciences, Inc. (Nasdaq: SAVA) ***announced positive clinical data today*** from an interim analysis of an open-label study with simufilam, the Company's investigational drug for the treatment of Alzheimer's disease.

In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved cognition in Alzheimer's patients, with no safety issues. Simufilam improved cognition scores 3.0 points on ADAS-Cog11, an 18% mean improvement, baseline to month 9 ($p < 0.001$). This interim analysis summarizes clinical data from the first 50 patients with mild-to-moderate Alzheimer's disease who completed 9 months of open-label simufilam treatment.

Cassava Sciences believes today's data is the first report of significant cognitive improvements at 9 months that also track with robust improvements in biomarkers in patients with Alzheimer's.

"We are very pleased with the overall consistency of data," said Remi Barbier, President & CEO. "Simufilam improved cognition, biomarkers and behavior, a triple-win for study participants. These clinical data combined with a clean safety profile and easy oral administration suggest highly encouraging and durable treatment effects for people living with Alzheimer's disease."

Alzheimer's is a progressive disease. Cognition will always decline over time. In patients with mild-to-moderate Alzheimer's disease, cognition scores decline over 4 points on ADAS-Cog over 9 months with over 90% certainty, as reported by the science literature.

Simufilam improved ADAS-Cog scores in 66% of patients at 9 months. An additional 22% of patients declined less than reported in the science literature at 9 months. Cognition outcomes suggest simufilam's treatment effects were broad-based.

Alzheimer's is often accompanied by behaviors disorders, such as anxiety, agitation or delusions. These may become more frequent as disease progresses. Simufilam reduced dementia-related behavior at 9 months on the Neuropsychiatric Inventory (NPI), a clinical tool widely used to measure changes in dementia-related behavior.

- At baseline, 34% of study subjects had no neuropsychiatric symptoms.
- At month 6, 38% of study subjects had no neuropsychiatric symptoms.
- At month 9, over 50% of study subjects had no neuropsychiatric symptoms.

The safety profile of simufilam in the interim analysis is consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

"Today's data with simufilam suggests disease modification," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique

mechanism of action has potential to provide transformative treatment benefits following 9 months of dosing.”

In February 2021, Cassava Sciences reported that simufilam improved cognition scores by 1.6 points on ADAS-Cog11, a 10% improvement, following six months of open-label treatment.

(Italicized emphasis added.)

61. On this news, the price per share of the Company’s common stock fell dramatically, from \$135.30 at the close of trading on July 28, 2021, to \$103.35 at the close of trading on July 29, 2021, to \$69.53 at the close of trading on July 20, 2021. Following the second July 29, 2021 press release, the price of Cassava’s stock declined approximately 48.6% over the two-day decline.

August 24, 2021 Press Release

62. On August 24, 2021, the Company issued a press release titled, “Cassava Sciences Announces Agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 Studies of Simufilam for the Treatment of Alzheimer’s Disease[.]”⁴² The press release stated, in relevant part:

. . . Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer’s disease, announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for both of its pivotal Phase 3 studies of oral simufilam for the treatment of patients with Alzheimer’s disease.

These SPA agreements document that FDA has reviewed and agreed upon the key design features of Cassava Sciences’ Phase 3 study protocols of simufilam for the treatment of patients with Alzheimer’s disease.

⁴² “Cassava Sciences Announces Agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 Studies of Simufilam for the Treatment of Alzheimer’s Disease”, CASSAVA SCIENCES, INC. (Aug. 24, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-agreement-fda-special-protocol>.

“I believe these SPAs mark a meaningful and encouraging milestone for Cassava Sciences,” said Remi Barbier, President & CEO. “The SPAs underscore our alignment with FDA on key scientific, clinical and regulatory requirements of our Phase 3 program of simufilam in Alzheimer’s disease.”

Cassava Sciences also reaffirmed prior guidance to advance simufilam into a Phase 3 pivotal program in Alzheimer’s disease in Fall 2021.

(Emphasis added.)

63. The above statements were materially false and misleading when made and failed to disclose that: (1) the quality and integrity of the data the Company used to support claims of simufilam’s efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company’s experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; and (5) due to the submission of manipulated data to the FDA, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam. Moreover, despite generalized risk statements in some of the Company’s public filings, the Individual Defendants failed to disclose to the investing public the specific risks that Cassava was facing due to its use of overstated and manipulated clinical trial data. Accordingly, the Individual Defendants’ positive statements about the Company’s business operations and prospects were materially false and misleading throughout the Relevant Period.

The Truth Begins to Emerge

August 24, 2021 Citizen Petition

64. On August 24, 2021, after the market closed, a citizen petition that had been submitted to the FDA – challenging the accuracy and integrity of clinical data supporting

simufilam – became publicly available.⁴³ The petition requested that the FDA “halt the current clinical studies of Simufilam . . . pending audits of (1) the publications relied on by Cassava in support of its scientific claims concerning Simufilam; (2) the IND [Investigation New Drug] application for Simufilam’s use in Alzheimer’s Disease; and (3) all clinical biomarker studies of Simufilam in Alzheimer’s Disease.”⁴⁴

65. In support of the request, the petition’s “Statement of Grounds”⁴⁵ section stated in pertinent part as follows:

Petitioner has enclosed with this Petition (and incorporates herein) a detailed technical report presenting *multiple reasons to question the quality and integrity of the research supporting Cassava’s claims about Simufilam’s use* for Alzheimer’s Disease. In sum, that report explains:

- (1) *All of the foundational science supporting Cassava’s claims about Simufilam’s use for Alzheimer’s Disease comes from a series of papers with two common co-authors (Dr. Hoau-Yan-Wang at City University of New York and Dr. Lindsay Burns of Cassava).* The studies of Drs. Wang and Burns were used by Cassava to obtain NIH grants and to open an Investigational New Drug (IND) application to study Simufilam. They form the foundation for the current clinical trials of Simufilam.
- (2) *No other lab has confirmed Cassava’s research connecting Filamin A to Alzheimer’s Disease, nor has any other lab confirmed that Simufilam binds or modifies Filamin A or has effects in Alzheimer’s Disease models.*
- (3) Close review of the data and analyses in the foundational research papers and Cassava’s recent publications of clinical trial analyses presents primary areas of concern:
 - a. The underlying papers of Drs. Wang and Burns involve extensive use of Western blot analyses to support their claims connecting Simufilam to Alzheimer’s. *Detailed analysis of the western blots in the published journal articles shows a*

⁴³ “Cassava Sciences Responds to Allegations”, CASSAVA SCIENCES, INC. (Aug. 25, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-responds-allegations>.

⁴⁴ See Citizen Petition (Aug. 18, 2021) at: <https://www.regulations.gov/document/FDA-2021-P-0930-0001> (last visited Dec. 20, 2021).

⁴⁵ *Id* at 3.

series of anomalies that are suggestive of systematic data manipulation and misrepresentation.

- b. Some of the foundational studies published by *Drs. Wang and Burns make claims about Simufilam's effects in experiments conducted on postmortem human brain tissue. The methodology allegedly used in those experiments defies logic, and the data presented again have the hallmarks of manipulation.*
 - c. Cassava's presentation of clinical biomarker data from the Phase 2b trials raises questions about the validity of the data. *The CSF samples in this study were first analyzed by an outside lab, which found that Simufilam was ineffective in improving the primary biomarkers end point and high variability in other biomarkers. But Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers. Cassava has not fully published the data from this reanalysis, but a presentation poster that it published on July 26, 2021, which appears to describe aspects of that work, shows signs of data anomalies or manipulation.*
- (4) *Six further aspects* of the research by Drs. Wang and Burns are incompatible with scientific norms, and these claims *raise further suspicions.*
- a. Remarkably High Affinity Binding Between PTI-125 and Filamin A.
 - b. Remarkably High Affinity Binding Between Naloxone and Filamin A
 - c. Isoelectric Focusing Experiments in Multiple Papers Indicate 100% of Filamin in Altered Conformation in Alzheimer's Disease and largely Restored to Correct Conformation by PTI125.
 - d. Novel Blood Diagnostic SavaDx Represents Plasma Filamin A Level
 - e. PTI-125/Simufilam Improves Memory in a Mouse Model of Alzheimer's Disease.
 - f. PTI-125/Simufilam Blocks the Interaction Between B-amyloid and $\alpha 7$ – Nicotinic Acetylcholine Receptors.

(Emphasis added.)

66. The forty-two-page attachment titled, "Statement of Concern Regarding the Accuracy and Integrity of Clinical and Preclinical Data Supporting the Ongoing Clinical Evaluation of Compound PTI-125, Also Known As Simufilam[.]"⁴⁶ and filed with and

⁴⁶ *Attachment 2 Statement of Concern Regarding the Accuracy and Integrity of Clinical and Preclinical Data Supporting the Ongoing Clinical Evaluation of Compound PTI-125, Also*

incorporated into the petition, further noted in its introduction:

In this document, *three primary concerns are raised*:

- The validity of clinical biomarker data: Biomarker analysis from patients treated with simufilam in Cassava’s double-blind study forms a primary basis of Cassava’s claim that simufilam engages its target in the central nervous systems, but *there are concerns about the integrity of this data. The CSF samples in this study were analyzed by an outside lab, which found that simufilam was ineffective* in improving the primary biomarker end point and showed high variability in other biomarkers. *However, Cassava Science had these samples bioanalyzed again and the data were finalized in an academic lab, which apparently refers to Dr. Wang. This re-analysis showed that simufilam rapidly and robustly improved a wide array of CSF biomarkers. Whereas Cassava has not fully published this reanalysis, Cassava’s 26 July 2021 poster presumably describing aspects of that work shows signs of data manipulation.*
- The integrity of western blot analyses: Western blotting was extensively used by Drs. Wang and Burns over the past 15 years to support their foundational scientific claims and underscores their SavaDx clinical plasma biomarker. *Detailed analysis of the western blots in the published journal articles from Drs. Wang and Burns shows a series of anomalies. The extent of these anomalies forms a 15-year pattern that strongly suggests systematic data manipulation and misrepresentation.*
- The integrity of analyses involving human brain tissue: Simufilam is reported to bind to its target and modify a range of downstream molecules in experiments conducted on post-mortem human brain tissue from subjects with Alzheimer’s disease and neurological controls. *The same human brain specimens are used across the studies from 2008-2017, so the results are premised on human neurons remaining viable up to 13 hours after death, then being successfully reanimated after nearly 10 years in frozen archival without any advanced cryopreservation techniques. The complex, multi-step cellular processes the authors claim to observe in tissue that has been dead for a decade are contrary to a basic understanding of neurobiology. As with the western blot data, there are anomalies in the presentation of the data which again strongly suggests manipulation.*

(Emphasis added.)

67. The citizen petition concluded that: “the extensive evidence set forth in the enclosed

Known As Simufilam re Citizen Petition from Labaton Sucharow, REGULATIONS.GOV, <https://www.regulations.gov/document/FDA-2021-P-0930-0004> (last visited Dec. 20, 2021).

report, which presents grave concerns about the quality and integrity of the scientific data supporting Cassava's claims for Simufilam's efficacy, provides compelling grounds for pausing the ongoing clinical trials until the FDA can conduct and complete a rigorous audit of Cassava's research."⁴⁷

August 25, 2021 Company Response

68. The next morning, premarket, Cassava, issued a response to the citizen petition.⁴⁸

The Company's response stated in pertinent part as follows:

Fiction: Biomarker data is generated by Cassava Sciences or its science collaborators and therefore are falsified.

Fact: Cassava Sciences' plasma p-tau data from Alzheimer's patients was generated by Quanterix Corp., an independent company, and presented at the recent Alzheimer's Association International Conference.

Fiction: Plasma p-tau for one individual Alzheimer's patient increased by 235%, which was not shown in the scatterplot.

Fact: This patient's plasma p-tau increased by 38%, not 235%, as shown in a scatterplot.

Fiction: Tissue staining showing Abeta42 inside neurons shows treatment effects.

Fact: Yes, Abeta42 is indeed inside neurons prior to plaque formation.

Fiction: The author's Citizen Petition to FDA dated August 18, 2021, is evidence of wrongdoing.

Fact: Five days after the Citizen's Petition, Cassava Sciences announced it had reached an agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 studies of simufilam for the treatment of Alzheimer's disease. The SPAs underscore alignment with FDA on key scientific, clinical and regulatory requirements of the Company's Phase 3 program of simufilam in Alzheimer's disease. Furthermore, a Citizen's Petition allows any party to raise safety/efficacy concerns with drugs the FDA is considering for approval, which is not the case for

⁴⁷ *Citizen Petition* at 3.

⁴⁸ "Cassava Sciences Responds to Allegations", CASSAVA SCIENCES, INC. (Aug. 25, 2021), <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-responds-allegations>.

Cassava Sciences' simufilem.

Fiction: Extensive use of Western blot analysis is foundational to Cassava Sciences' research and therefore suspicious.

Fact: Western blot analysis is foundational to the biotechnology industry. Western blotting is a standard lab technique used world-wide to detect a protein of interest.

Fiction: Cassava Sciences' Western blots data appear overexposed and highly processed, evidence of image manipulation.

Fact: High quality bands are supposed to look sharp. Smudged bands can be evidence of inexperience, depending on levels of protein in the band.

Fiction: Western blots data are identical, more evidence of image manipulation.

Fact: The Western blots bands shown in the allegation are control bands. Control bands are supposed to be highly similar (since they show equal amounts of protein between lanes). Bands show clear differences when expanded. In addition, image manipulation of control bands makes no sense since these would not change the end data.

Fiction: "Halo" effects in certain bands indicate fraud.

Fact: A "Halo" effects in certain bands is a direct result of very dense dark loading control bands.

Fiction: Unusual looking bands on Western blots were pieced together from multiple sources.

Fact: Proteins can and do stick to the side of a lane and migrate that way, resulting in 'candy-wrapper' appearance or other fictional images.

Fiction: Femtomolar binding affinity is unusual and suspicious.

Fact: Femtomolar binding affinity is a fundamental property of simufilem and may account for its relative potency and safety.

Fiction: Post-mortem brain tissue that is dead for a decade is unreliable.

Fact: Because of the inaccessibility of the human brain and its unavailability for biopsy, translational medicine can rely on post-mortem tissue. In our case, human brain tissue was collected within 6 hours of death, flash-frozen and stored at -80 Centigrade. This is a standard procedure for pathologists. Such tissue processing is also used in cancer and other fields. Cassava Sciences is not aware of an industry-wide 'expiration date' on human post-mortem brain tissue that is properly collected,

processed and stored.

Fiction: Isoelectric focusing gels should not have crisp bands, which is evidence of fraud.

Fact: Quality isoelectric focusing gels often do have crisp bands.

Fiction: Changes in the Y-maze test for transgenic mice could be interpreted as a decline in cognition.

Fact: A panel of independent, peer-reviewers believe these changes represent an improvement, along with significant improvements in two other behavior tests.

Fiction: High-affinity binding of naloxone for filamin A is suspicious.

Fact: Naloxone binds the same site on filamin A. Of course, it will have high-affinity binding.

Fiction: Isoelectric focusing experiments indicate 100% of filamin A is in altered conformation in Alzheimer's disease and is largely restored to correct conformation by simufilam.

Fact: Cassava Sciences agrees. This nicely describes the mechanism of action for simufilam.

(Italicized emphasis added.)

69. Despite the Company's response, the market negatively received the news disclosed on August 24, 2021 and August 25, 2021. The price per share of the Company's common stock dropped from \$117.83 at the close of trading on August 24, 2021 (prior to public disclosure of the citizen petition) to \$80.86 at the close of trading on August 25, 2021. This \$36.97 decline marked an approximately 31.4% one-day decrease in value.

70. Still though, the Company's stock price remained at inflated levels because the Company's response to the allegations contained false and misleading statements. Specifically, the August 25, 2021 response failed to disclose that Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness, as the Company had

claimed. Quanterix merely conducted the biomarker tests which generated the raw data which the Company analyzed and synthesized into the form presented at the Alzheimer's Association International Conference. Thus, the Company's framing of Quanterix's involvement as a shield to the allegations in the citizen petition was also false and misleading.

The Truth Fully Emerges

71. On August 27, 2021, Quanterix Corporation issued a statement in response to Cassava's press release concerning the citizen petition allegations.⁴⁹ In Quanterix's statement, the Company clarified its involvement in the creation of the data the Company had presented at the Alzheimer's Association International Conference.⁵⁰ Quanterix's statement said as follows, in relevant part:

Quanterix [], a company digitizing biomarker analysis to advance the science of precision health, today released the following statement in response to news reports related to Cassava Sciences.

Cassava previously engaged Quanterix' Accelerator laboratory to perform sample testing based on blinded samples provided by Quanterix. ***Quanterix or its employees did not interpret the test results or prepare the data charts presented by Cassava at the Alzheimer's Association International Conference (AAIC) in July 2021 or otherwise.***

Quanterix is widely recognized for its commitment to business integrity and to upholding the highest standards of quality...

(Emphasis added.)

72. The Company also issued a press release that same day,⁵¹ finally admitting that

⁴⁹ "Quanterix Releases Statement", QUANTERIX CORPORATION, <https://www.quanterix.com/press-releases/quanterix-releases-statement/> (Aug. 27, 2021).

⁵⁰ *Id.*

⁵¹ "Cassava Sciences Releases Statement Regarding Plasma p-tau Analysis from a Previously Disclosed Phase 2b Clinical Study in Alzheimer's Patients, CASSAVA SCIENCES, INC., <https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-releases-statement-regarding-plasma-p-tau> (Aug. 27, 2021).

Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness, as the Company had previously claimed. The press release stated, in relevant part:

Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today released a statement regarding plasma p-tau analysis from a previously disclosed randomized, controlled Phase 2b clinical study in patients with Alzheimer's disease. For this study, Cassava Sciences contracted with Quanterix Corp., a highly regarded, independent laboratory, to perform sample testing on blinded samples.

The Phase 2b clinical study was conducted by Cassava Sciences. ***Quanterix' sole responsibility with regard to this clinical study was to perform sample testing, specifically, to measure levels of p-tau in plasma samples collected from study subjects.***

"To ensure data integrity, it is standard industry practice to keep separate the people who generate the data from the people who analyze the data," said Remi Barbier, President & CEO. "That certainly was the case here. Anything different is a distortion of the facts."

Quanterix' sample testing was conducted entirely by its employees. Quanterix' employees were blind to treatment group, i.e., they did not know which samples were from placebo, or simufilam-treated patients. ***Quanterix conducted sample testing, then sent raw data to Cassava Sciences for analysis of treatment effects. Eventually, Cassava Sciences presented these data in a poster presentation at the Alzheimer's Association International Conference (AAIC) in July 2021.*** In keeping with scientific authorship guidelines, prior to submitting the abstract to AAIC, Cassava Sciences received permission from Quanterix to include its lab personnel in the author list.

Cassava Sciences is aware of allegations that are being made by a party that yesterday admitted it holds a short position in the Company's stock. (A short position allows an investor to profit from a drop in the Company's stock price.) Cassava Sciences believes claims made by this party regarding scientific integrity are false and misleading. The Company stands behind its science, its scientists and its scientific collaborators, and is responding to ensure the facts are known and respected.

(Emphasis added.)

73. Despite Cassava's attempts to distance itself from allegations about the integrity of its data, on this news, the Company's share price declined by \$12.51 per share—approximately

17.7%—from its August 26, 2021 closing price of \$70.85 per share to close August 27, 2021 at \$58.34. The Company’s share price has declined by a total of \$59.49, or approximately 50.49%, from the time the citizen petition was published after the close of the markets on August 24, 2021 until the close of trading on August 27, 2021.

The False and Misleading Proxy Statement

74. In addition to the above false and misleading statements issued and/or caused to be issued by the Individual Defendants, the Individual Defendants caused the Company to issue a false and misleading proxy statement during the Relevant Period. There was one Form DEF 14A filed with the SEC on March 31, 2021 during the Relevant Period before the truth fully emerged (the “2021 Proxy”).⁵²

75. The 2021 Proxy recommended shareholders vote to, *inter alia*, reelect Defendants Barbier, Robertson, and Scannon to the Board.⁵³ The 2021 Proxy also recommended shareholders to vote: to approve an amendment to the Company’s 2018 Omnibus Incentive Plan (the “2018 Plan”) to add an additional 4 million shares to the 2018 Plan for issuance to Company employees, directors, and consultants; vote to ratify Ernst & Young LLP as the Company’s independent auditor for the fiscal year ending December 31, 2021; and vote to approve, by a nonbinding advisory vote, the 2020 executive compensation for Defendants Barbier, Friedmann, and Schoen.⁵⁴

76. The 2021 Proxy noted the following concerning the Board’s risk oversight

⁵² These proxy allegations are based solely on negligence, they are not based on any allegations of recklessness or knowing conduct by or on behalf of the Individual Defendants, and they did not allege fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to the proxy allegations and related claims.

⁵³ Cassava Sciences, Inc. 2021 Proxy, CASSAVA SCIENCES, INC. (Dec. 31, 2020), <https://www.cassavasciences.com/node/15261/html>

⁵⁴ *Id.*

functions:

The Board of Directors maintains a structure with the Chief Executive Officer of the Company holding the position as Chairman of the Board of Directors, and with an Audit Committee and Compensation Committee for oversight of specific areas of responsibility, discussed further below. The Company does not have a lead independent director. ***The Company believes that this structure is appropriate and allows for efficient and effective oversight,*** given the Company's relatively small size (both in terms of number of employees and in scope of operational activities directly conducted by the Company), its corporate strategy (including the use of outsourcing for certain activities) and its focus on drug and diagnostic research and development. ***The Chairman, President and Chief Executive Officer, the Committees of the Board of Directors and, as needed, other executive officers and employees of the Company provide the Board of Directors with information regarding the Company's risks. The Board of Directors, or the Committee with special responsibility for oversight of the area implicated by the highlighted risks, then uses this information to perform its oversight role and inform its decision making with respect to such areas of risk.***

(Emphasis added).

77. The 2021 Proxy did not disclose, however, that (1) the quality and integrity of the data the Company used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue was contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective; (5) due to the foregoing and submission of manipulated data to the FDA, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (6) the Company failed to maintain internal controls.

78. Additionally, the 2021 Proxy contained descriptions for the Audit Committee and Compensation Committee, stating in pertinent part as follows:

The Board of Directors has a standing Audit Committee that oversees the Company's accounting and financial reporting processes and audits of the Company's financial statements. The Company also has a standing Compensation Committee. The Board of Directors does not have a lead director or a standing

Nominating Committee. Mr. Barbier is the Chairman of the Board of Directors, President and Chief Executive Officer of the Company.

The Audit Committee consists of directors Dr. Gussin, Mr. Robertson and Dr. Scannon. . . . The Board of Directors of the Company has determined that these individuals are independent as defined under the Nasdaq Stock Market LLC listing standards as well as the SEC rules. The Board of Directors has also determined that Mr. Robertson is an “audit committee financial expert” as defined in the SEC rules. The Audit Committee operates under a written charter adopted by the Board of Directors. The Company maintains a copy of the Audit Committee charter on its website: www.cassavasciences.com. The Audit Committee reviews the Company’s internal accounting procedures, consults with and reviews the services provided by the Company’s independent registered public accounting firm and makes recommendations to the Board of Directors regarding the selection of the independent registered public accounting firm. The Audit Committee held four meetings during fiscal year 2020.

The Compensation Committee consists of directors Dr. Gussin and Mr. Robertson. The Board of Directors of the Company has determined that these individuals are independent as defined under the Nasdaq Stock Market LLC listing standards. ***The Compensation Committee reviews and recommends to the Board of Directors the salaries, incentive compensation and benefits of the Company’s officers and administers the Company’s stock plans and employee benefit plans.*** Refer to the section entitled “Compensation Discussion and Analysis” for more information about the Company’s Compensation Committee and its processes and procedures. The Compensation Committee operates under a written charter adopted by the Board of Directors. The Company maintains a copy of the Compensation Committee charter on its website: www.cassavasciences.com. The Compensation Committee held three meetings during fiscal year 2020.

(Emphasis added.)

79. The 2021 Proxy was false and misleading because, while it assured investors that, it would keep stockholders informed and that its Audit Committee and Compensation Committee reviewed filings, including the 2020 10-K, that was not the case as revealed by the Citizen Petition dated August 18, 2021, and Quanterix’s Statement dated August 27, 2021. The citizen petition and Quanterix’s statement clearly shows that the Individual Defendants allowed each other and the Company to issue false and materially misleading statements during the Relevant Period. The Individual Defendants also recommended shareholders elect directors during the Relevant Period

via the 2021 Proxy.

80. As a result of the material misstatements and omissions contained in the 2021 Proxy, Company shareholders reelected Defendants Barbier, Robertson, and Scannon to the Board, allowing them to continue breaching their fiduciary duties to Cassava; ratified Ernst & Young LLP as independent auditor, and approved, on a nonbinding advisory basis, the 2020 compensation Defendants Barbier, Friedmann, and Schoen. Company shareholders did not approve the amendment to the 2018 Plan.

FIDUCIARY DUTIES

81. By reason of their positions as officers and directors of the Company, each of the Individual Defendants owed and continues to owe Cassava and its stockholders fiduciary obligations of trust, loyalty, good faith, and due care and must use his or her utmost ability to control and manage Cassava in a fair, just, honest, and equitable manner. The Individual Defendants must at all times act in furtherance of the best interests of Cassava and its stockholders to benefit all stockholders equally and not in furtherance of their personal interest or benefit.

82. Each Individual Defendant owes and continues to owe Cassava, and its stockholders, the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets.

83. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Cassava, were able to, and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their positions with Cassava, each of the Individual Defendants had knowledge of material, nonpublic information regarding the Company. In addition, as officers and/or directors of a publicly held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information regarding the Company's business practices, operations, financials, financial prospects, compliance policies, and

internal controls so that the market price of the Company's stock would be based on truthful and accurate information.

84. To discharge their duties, the Individual Defendants must exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. The Individual Defendants were required to, among other things:

- ensure that the Company complied with its legal obligations and requirements—including requirements involving the filing of accurate financial and operational information with the SEC—and refrain from engaging in insider trading and other deceptive conduct;
- conduct the affairs of the Company in compliance with all applicable laws, rules, and regulations to make it possible to provide the highest quality performance of its business, avoid wasting the Company's assets, and maximize the value of the Company's stock;
- remain informed as to how Cassava conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make a reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with applicable laws; and
- truthfully and accurately guide investors and analysts as to the business operations of the Company at any given time.

Duties Pursuant to the Company's Code of Ethics

85. The Individual Defendants, as officers and/or directors of Cassava, were bound by the Company's Code of Ethics,⁵⁵ which required the following, among other things:

It is the policy of Cassava Sciences, Inc. (together with its wholly- and majority owned subsidiaries and affiliates worldwide, the "Company") that all directors, officers and employees of the Company shall, to the best of their knowledge and ability, adhere to, comply with and advocate the principles set out in this code of

⁵⁵ See Cassava Sciences, Inc. Code of Ethics: <https://www.cassavasciences.com/static-files/2d65c66e-3def-4790-aaa4-172a30e9eac2>.

ethics (the “Code”) governing their professional and ethical conduct in the fulfillment of their responsibilities.

The purposes of the Code are to:

- Promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Promote full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to the U.S. Securities and Exchange Commission and in other public communications made by the Company;
- Promote compliance with applicable governmental laws, rules and regulations;
- Promote the prompt internal reporting of violations of the Code to appropriate persons of authority within the Company; and
- Promote accountability for adherence to the Code.

The Code embodies principles to which all directors, officers and employees are expected to adhere and advocate. Any violations of the Code may result in disciplinary action, up to and including termination or removal, as applicable.

All directors, officers and employees of the Company will:

1. Act with honesty and integrity, avoiding actual or apparent conflicts between personal and the interests of the Company, including refraining from receiving improper personal benefits as a result of holding a particular position with the Company;

* * *

3. Where applicable, provide the U.S. Securities and Exchange Commission (the “Commission”) and the public with complete, fair, accurate, timely and understandable disclosure in periodic reports and other documents filed or submitted to the Commission and in other public communications;
4. Endeavor to comply with applicable laws and regulations of federal, state, local and foreign governments and government agencies having jurisdiction over the Company, and with applicable regulations of private or self-regulatory authorities having jurisdiction over the Company;
5. Act in good faith, responsibly with due care and diligence and without misrepresentation or omission of material facts and strive to maintain

independent judgment in the performance and fulfillment of their duties and responsibilities;

6. Promote ethical behavior among subordinates and peers at the Company;

* * *

10. Comply with other policies and procedures of the Company applicable to their positions and employment, including the Company's Insider Trading Policy and, to the extent applicable, the other policies and procedures of the Company set forth in the Company's Employee Handbook.

* * *

It is the duty of each director, officer and employee of the Company to report violations of the Code promptly to the attention of the Company's Chief Executive Officer, Chief Financial Officer or to any member of the Audit Committee of the Board (the "Audit Committee").

86. The Individual Defendants failed to adhere to the Code of Ethics when they failed to correct their false and misleading statements made to the investing public.

Duties Pursuant to the Company's Audit Committee Charter

87. In addition to these duties, the Audit Committee Defendants, who served on the Audit Committee during the Relevant Period, owed specific duties to Cassava under the Audit Committee Charter (the "Audit Charter").⁵⁶ Specifically, the Audit Charter provided for the following responsibilities of the Audit Committee Defendants:

PURPOSES

The purpose of the Audit Committee of the Board of Directors of Cassava Sciences, Inc., a Delaware corporation (the "Company"), shall be to make such examinations as are necessary to monitor the Company's system of internal controls, to provide the Company's Board of Directors with the results of its examinations and recommendations derived therefrom, to outline to the Board of Directors improvements made, or to be made, in internal accounting controls, to nominate independent auditors and to provide to the Board of Directors such additional information and materials as it may deem necessary to make the Board of Directors aware of significant financial matters which require the Board of Director's attention. In addition, the Audit Committee will undertake those specific

⁵⁶ See Cassava Sciences, Inc. Audit Charter: <https://www.cassavasciences.com/static-files/f82696dc-8d9d-483f-81e0-6bd40ae3ecde>.

duties and responsibilities listed below and such other duties as the Board of Directors may from time to time prescribe.

* * *

RESPONSIBILITIES

The responsibilities of the Audit Committee shall include:

1. Reviewing on a continuing basis the adequacy of the Company's system of internal controls;
2. Reviewing on a continuing basis the activities, organizational structure and qualifications of the Company's internal audit function;
3. Reviewing the independent auditors' proposed audit scope, approach and independence;
4. Conducting a post-audit review of the financial statements and audit findings, including any significant suggestions for improvements provided to management by the independent auditors;
5. Reviewing the performance of the independent auditors, who shall be accountable to the Board of Directors and the Audit Committee;
6. Recommending the appointment of independent auditors to the Board of Directors;
7. Reviewing fee arrangements with the independent auditors;
8. Reviewing before release the audited financial statements and Management's Discussion and Analysis in the Company's annual report on Form 10-K;
9. Reviewing before release the unaudited quarterly operating results in the Company's quarterly earnings release;
10. Overseeing compliance with the requirements of the Securities and Exchange Commission for disclosure of independent auditor's services and audit committee members and activities;
11. Overseeing of compliance with the Company's Standards of Business Conduct and with the Foreign Corrupt Practices Act;
12. Reviewing, in conjunction with counsel, any legal matters that could have a significant impact on the Company's financial statements;

13. Providing oversight and review of the Company's asset management policies, including an annual review of the Company's investment policies and performance for cash and short-term investments;
14. If necessary, instituting special investigations and, if appropriate, hiring special counsel or experts to assist;
15. Reviewing related party transactions for potential conflicts of interest;
16. Providing a report in the Company's proxy statement in accordance with the requirements of Item 306 of Regulations S-K and S-B and Item 7(e)(3) of Schedule 14A; and
17. Performing other oversight functions as requested by the full Board of Directors.

88. The Individual Defendants failed to adhere to the Code of Ethics by issuing false and materially misleading public statements and filings with the SEC related to the manipulation of data the Company used, and submitted to the FDA, to overstate simufilam's effectiveness. Furthermore, the Audit Committee Defendants failed to uphold their duties required by the Audit Charter by allowing the Company to issue materially false and misleading statements regarding the manipulated data used to overstate the efficacy of simufilam to the investing public and the FDA.

BREACHES OF DUTIES

89. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as officers and/or directors of Cassava, the absence of good faith on their part, and a reckless disregard for their duties to the Company.

90. The Individual Defendants breached their duties of loyalty and good faith by utterly failing to implement a reasonable, relevant, meaningful, and well-constituted system of internal controls, especially with respect to disclosure of material information regarding manipulated and overstated data that purportedly demonstrated the efficacy of the Company's lead therapeutic

product candidate, as described herein. The Individual Defendants also breached their duties of loyalty and good faith by allowing or causing the Company to make improper statements to the public and the Company's stockholders. These unlawful practices caused Cassava substantial damage.

91. The Audit Committee Defendants had a duty to review the Company's earnings press releases and regulatory filings. The Audit Committee Defendants breached their duties of loyalty and good faith by approving the omission of material information, making the improper statements detailed herein, and failing to properly oversee Cassava's public statements and internal control function.

92. The Individual Defendants, because of their positions of control and authority as officers and/or directors of Cassava, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein. The Individual Defendants also failed to prevent the other Individual Defendants from taking such illegal actions. In addition, because of the Individual Defendants' improper course of conduct, the Company is now the subject of the Federal Securities Class Actions, which allege violations of federal securities laws. As a result, Cassava has expended, and will continue to expend, significant sums of money.

DAMAGES TO CASSAVA

93. The submission of manipulated data to the FDA and failure to correct false and misleading statements during the Relevant Period has exposed the Company to myriad reputational and financial damages, including but not limited to:

- (a) Possible loss of crucial funding for future drug trials;
- (b) Liability arising from the Federal Securities Class Actions;
- (c) The loss of credibility with customers and suppliers; and

- (d) Legal costs associated with litigation, investigations, and restatements.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

94. Plaintiff brings this action derivatively and for the benefit of Cassava to redress injuries suffered, and to be suffered, because of the Individual Defendants' breaches of their fiduciary duties as directors and/or officers of Cassava, unjust enrichment, and violations of Sections 14(a) and 20(a) of the Exchange Act.

95. Cassava is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

96. Plaintiff is, and has been continuously at all relevant times, a stockholder of Cassava. Plaintiff will adequately and fairly represent the interests of Cassava in enforcing and prosecuting its rights, and, to that end, has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

97. Plaintiff incorporates by reference and re-alleges each allegation stated above as if fully set forth herein.

98. A pre-suit demand on the Board of Cassava is futile and, therefore, excused. At the time of filing this action, the Board consists of seven directors: (i) Barbier; (ii) Friedmann; (iii) Gussin; (iv) O'Donnell; (v) Roberts; and (vi) Scannon, as well as non-party (vii) Richard J. Barry. Plaintiff needs only to allege demand futility as to a majority of the Board at the time this action is commenced.

99. Demand is excused as to all of the Director Defendants (*i.e.*, Barbier, Friedmann, Gussin, O'Donnell, Roberts and Scannon) because each one of them faces a substantial likelihood of liability because they made or caused the Company to make false and misleading statements and omissions of material facts as set forth herein.

100. In complete abdication of their fiduciary duties, the Director Defendants knowingly or recklessly made or caused the Company to make the materially false and misleading statements alleged herein to make the Company appear more successful, profitable and attractive to investors. As a result of the foregoing, the Director Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile and thus excused.

101. Demand on Defendant Barbier is further futile. Barbier has served as the Company's President, CEO, and as a Company director since Cassava's inception in May 1998.⁵⁷ As such, he is not an independent director as the Company acknowledges.⁵⁸ He has received and continues to receive compensation for his role as a director as described herein and has been Chairman of the Board since May 1998.⁵⁹ As such, Barbier received a material personal benefit as result of the misconduct alleged herein via his compensation from the Company, particularly in the form of stock, the value of which was artificially inflated as a result of the false and misleading statements and other misconduct alleged herein. Moreover, Barbier signed and thus personally made the false and misleading statements in the 2021 Proxy. As such, Barbier faces a substantial likelihood of liability on the claims brought herein. Defendant Barbier is also a named defendant in all of the Federal Securities Class Actions. As CEO and President, Defendant Barbier was ultimately responsible not only for the statements he personally made throughout the Relevant Period (including those in various press releases and statements in the 2020 10-K, for which he signed SOX certifications) but also was responsible for all of the false and misleading statements

⁵⁷ Cassava Sciences, Inc. 2021 Proxy (Form DEF 14A) (Dec. 31, 2020) at 15: <https://www.cassavasciences.com/node/15261/html>.

⁵⁸ See Cassava 2021 Proxy at 16, 29.

⁵⁹ *Id.*

and omissions that were made during the Relevant Period. In addition, the 2021 Proxy was solicited on his behalf, and the false and misleading statements contained therein contributed both to his reelection to the Board and also to shareholders approving, on an advisory basis, his unjust compensation. As the Company's highest officer and as trusted Chairman of the Board, he conducted little, if any, oversight of the Company's internal controls which resulted in its submission of manipulated data to the FDA and making false and misleading statements, consciously disregarded his duties to monitor internal controls, and consciously disregarded his duties to protect corporate assets. Defendant Barbier thus faces a substantial likelihood of liability on the claims brought herein.

102. Demand on Defendant Friedmann is further futile. Friedmann has served as a Company director since September 1998 and as the Company's CMO since 2001.⁶⁰ Thus, as the Company admits, he is not considered independent.⁶¹ The Company provides Defendant Friedmann with his principal occupation, for which he receives handsome compensation. Accordingly, and as the owner of 1.4% of the Company's issued and outstanding stock, Friedmann received a material personal benefit as a result of the misconduct alleged herein, as the value of the Company's stock was artificially inflated as a result of the false and misleading statements and other misconduct alleged herein. In addition, Defendant Friedmann personally made false and misleading statements in multiple press releases during the Relevant Period and signed, and thus personally made, the false and misleading statements contained in the Company's 2020 10-K.⁶² Further, the 2021 Proxy was solicited on Friedmann's behalf and the false and misleading

⁶⁰ *See id.* at 15.

⁶¹ *See id.* at 20, 29.

⁶² *See* Casava 2020 10-K.

statements contained therein contributed to shareholders approving, on an advisory basis, his handsome compensation. As CMO and a trusted Company director, he conducted little, if any, oversight of the Company's internal controls which resulted in its submission of manipulated data to the FDA and making false and misleading statements. In doing so, Friedmann consciously disregarded his duties to monitor internal controls, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Friedmann is a defendant in two of the three Securities Class Actions. Friedmann thus faces a substantial likelihood of liability on the claims brought herein.

103. Demand on Defendant Gussin is further futile because he signed and, as such, personally made the false and misleading statements contained in the 2020 10-K.⁶³ Furthermore, the 2021 Proxy, which also contained false and misleading statements, was solicited on Gussin's behalf. Defendant Gussin thus faces a substantial likelihood of liability on the claims brought herein. In addition, Gussin received a material personal benefit as a result of the misconduct alleged herein as the owner of 119,225 shares of Company stock, the value of which was artificially inflated as a result of the false and misleading statements and other misconduct described herein.

104. Demand on Defendant O'Donnell is further futile because he signed, and thus personally made, the false and misleading statements contained in the 2020 10-K.⁶⁴ Similarly, the 2021 Proxy, which contained false and misleading statements, was solicited on his behalf.⁶⁵ Defendant O'Donnell thus faces a substantial likelihood of liability on the claims brought herein. In addition, O'Donnell received a material personal benefit as a result of the misconduct alleged

⁶³ See Cassava 2020 10-K.

⁶⁴ See Cassava 2020 10-K.

⁶⁵ See Cassava 2021 Proxy.

herein as the owner of 83,223 shares of Company stock, the value of which was artificially inflated as a result of the false and misleading statements and other misconduct described herein.

105. Demand on Defendant Robertson is further futile because he signed, and thus personally made, the false and misleading statements contained in the 2020 10-K.⁶⁶ Moreover, the 2021 Proxy was solicited on his behalf, and the false and misleading statements contained therein contributed to his reelection to the Board. Defendant Robertson thus faces a substantial likelihood of liability on the claims brought herein. In addition, Robertson received a material personal benefit as a result of the misconduct alleged herein as the owner of 1,027,943 shares of Company stock, the value of which was artificially inflated as a result of the false and misleading statements and other misconduct described herein.

106. Demand on Defendant Scannon is further futile because he signed, and thus personally made, the false and misleading statements contained in the 2020 10-K.⁶⁷ Furthermore, the 2021 Proxy was solicited on his behalf, and the false and misleading statements contained therein contributed to his reelection to the Board. Defendant Scannon thus faces a substantial likelihood of liability on the claims brought herein. In addition, Scannon received a material personal benefit as a result of the misconduct alleged herein as the owner of 89,144 shares of Company stock, the value of which was artificially inflated as a result of the false and misleading statements and other misconduct described herein.

107. As trusted Company directors, the above directors conducted little, if any, oversight of the Company's internal controls which resulted in its submission of manipulated data to the FDA and making false and misleading statements described herein, consciously disregarded their

⁶⁶ See Cassava 2020 10-K.

⁶⁷ See Cassava 2020 10-K.

duties to monitor such controls, and consciously disregarded their duties to protect corporate assets. This not only breached their fiduciary duties but also violated the Company's Code of Ethics. Accordingly, the Director Defendants face a substantial likelihood of liability in this action.

108. Pursuant to the Company's Audit Charter, the Audit Committee Defendants (Gussin, Robertson and Scannon) are responsible for overseeing, among other things, the integrity of the Company's financial statements, the Company's compliance with laws and regulations, and the Company's accounting and financial reporting practices and system of internal controls. The Audit Committee Defendants failed to ensure the integrity of the Company's financial statements and internal controls, as they are charged to do under the Audit Charter, and allowed the Company to issue false and misleading financial statements with the SEC. Thus, the Audit Committee Defendants further face a substantial likelihood of liability in this action.

FIRST CLAIM

Against the Director Defendants *for Violations of Section 14(a) of the Exchange Act*

109. Plaintiff repeats and re-alleges each and every allegation set forth above, as though fully set forth herein.

110. The Section 14(a) Exchange Act claims alleged herein are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants. The Section 14(a) claims alleged herein do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these non-fraud claims.

111. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that "[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate

commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l].”

112. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. § 240.14a-9.

113. The 2021 Proxy made numerous false and misleading statements and omissions as set forth above.

114. In the exercise of reasonable care, the Director Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2021 Proxy were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for stockholder determination in the 2021 Proxy including, but not limited to, election of directors, ratification of an independent auditor, and the approval of executive compensation.

115. The Company was damaged as a result of the Director Defendants’ material misrepresentations and omissions in the 2021 Proxy.

116. Plaintiff, on behalf of Cassava, has no adequate remedy at law.

SECOND CLAIM

Against the Director Defendants *for Violations of Section 20(a) of the Exchange Act*

117. Plaintiff repeats and re-alleges each and every allegation set forth above, as though fully set forth herein.

118. The Director Defendants, by virtue of their positions with Cassava and their specific acts, were, at the time of the wrongs alleged herein, controlling persons of Cassava and officers and directors who made the false and misleading statements alleged herein within the meaning of § 20(a) of the Exchange Act. The Individual Defendants had the power and influence, and exercised same, to cause Cassava to engage in the illegal conduct and practices complained of herein.

119. Plaintiff, on behalf of Cassava, has no adequate remedy at law.

THIRD CLAIM

Against the Individual Defendants *for Breach of Fiduciary Duty*

120. Plaintiff repeats and re-alleges each and every allegation set forth above, as though fully set forth herein.

121. As officers and directors of the Company, the Individual Defendants owed and continue to owe fiduciary obligations to Cassava and its stockholders. By reason of their fiduciary relationships, the Individual Defendants owed and continue to owe Cassava the highest obligations of good faith, fair dealing, loyalty, oversight, and due care.

122. The Individual Defendants either knew of, or in bad faith through a conscious disregard of their duties, permitted the conduct alleged herein. Notwithstanding that compliance with regulations is mission critical for a highly regulated pharmaceutical company like Cassava,

the Individual Defendants failed to implement, execute and/or maintain appropriate Board-level oversight over the Company's submission of data to the FDA to ensure the Company's compliance with applicable regulations.

123. The failure to implement, execute and/or maintain appropriate Board-level oversight over the Company's submission of data to the FDA in connection with Cassava's lead therapeutic product candidate was not a good-faith exercise of business judgment to protect and promote the Company's corporate interests. Accordingly, the Individual Defendants breached their duties of care and loyalty to the Company.

124. Cassava has sustained significant damages as a result of the Individual Defendants' misconduct.

125. Plaintiff, on behalf of Cassava, has no adequate remedy at law.

FOURTH CLAIM

Against the Individual Defendants *for Unjust Enrichment*

126. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

127. By their wrongful acts, violations of law, false and misleading statements, and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense and to the detriment of Cassava.

128. The Individual Defendants either benefitted financially from the improper conduct, received unjust compensation tied to the false and misleading statements, received bonuses, equity awards, or other compensation from Cassava tied to the performance or artificially inflated valuation of Cassava, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct during the Relevant Period.

129. Plaintiff, on behalf of Cassava, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows:

- A. Declaring that Plaintiff may maintain this action on behalf of Cassava, and that Plaintiff is an adequate representative of the Company;
- B. Finding that the Individual Defendants have breached their fiduciary duties to Cassava;
- C. Determining and awarding to Cassava the damages sustained by it because of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre- and post-judgment interest thereon;
- D. Directing Cassava and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and protect Cassava and its stockholders from a repeat of the damaging events described herein;
- E. Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and
- F. Granting such other and further relief as the Court may deem just and proper.

Dated: January 11, 2022

Respectfully submitted,

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